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| 10/799,931 | 03/12/2004 | Christopher Gerard Quinn | 021628-000910US | 6832 |

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| EXAMINER |
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NASSER, ROBERT L

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| ART UNIT | PAPER NUMBER |
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3735

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/03/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/799,931

Applicant(s)

QUINN ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become **ABANDONED** (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-34 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 9-18 and 20-27 is/are rejected.
- 7) ☒ Claim(s) 6, 8, 19 and 28-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/22/2004.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 2, 4, 13, 15, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Brockway et al 4846191. Brockway shows a device with a pressure sensor 16, a pressure transmission catheter 20 having a proximal portion, a mid portion, and distal portion, a distal port, and a lumen extending thereto, where the proximal portion connects to the pressure sensor, a pressure transmission fluid in the lumen, a barrier 30 in the distal port to retain fluid in the lumen, where the distal end has a larger inside diameter than the mid portion does. Claim 2 is rejected in that the device is connected to a telemetry unit (see column 5, lines 20-22). Claim 4 is rejected in that the distal end is counter-bored, or at least has equivalent structure to a counter bore, to create the larger diameter. The examiner notes that the method of forming the structure is a product by process limitation and will not serve to define over equivalent structure formed a different way. Claim 13 is rejected in that in figure 4, Brockway has a gel barrier that is recessed. Claim 15 is rejected in that the distal port is distal facing. Claims 22 and 23 are rejected for the reasons given above.

Claims 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Itoigawa et al 6019729. Itoigawa shows a catheter 3, with an open proximal end

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connected to sensor 12, and a distal end closed by a cap that is an integral extension of the catheter, and a lumen filled with a pressure transmitting liquid.

Claims 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackson 4160448. Jackson shows a OTC with a catheter having an open proximal end connected to a pressure sensor 17, a fluid in the lumen, and a distal end closed by a sleeve 12 over the exterior of the catheter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191. Claim 3 is rejected in that the exact method of forming the larger diameter has not been stated to be for a particular reasons or to solve a stated problem. As such, the method of forming the larger diameter would have been a mere matter of design choice for one skilled in the art. Claim 21 is rejected in that the exact shape of the lumen has not been stated to be for a particular reasons or to solve a stated problem. As such, the shape of the lumen would have been a mere matter of design choice for one skilled in the art.

Claims 5 and 10-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Brockway et al 6296615. With respect to claim 5, Brockway et al '615 further teaches providing a surface modification, such as an

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antithrombotic coating, to increase the hemo-compatibility of the system (see column 6, lines 36-49). Hence, it would have been obvious to modify Brockway '191 to use such a coating, to increase the hemo-compatibility. Claim 10 is rejected in that the coating is a layer. Claims 11 and 12 are rejected in that Brockway '615 further teaches providing a removable tube over the end of the device to protect the end prior to use (see column 6, lines 50-58). As such, it would have been obvious to modify Brockway '191 to use such a cover, to provide protection for the tip. The tube is only connected at the distal end.

Claims 5, 7, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Cohen et al 6712772. Cohen et al further teaches providing a tube over the exterior of a catheter to prevent the migration of contaminants (see column 13, lines 39-45). As such, it would have been obvious to modify Brockway '191 to use such a tube, to prevent contamination of the catheter.

Claims 5, 9, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Brockway et al 6409674. Brockway further teaches a stabilizer attached to a catheter to enhance the anchoring of the device and prevent movement in use. As such, it would have been obvious to modify Brockway to provide a stabilizer, to improve the measurement process. With respect to claim 17, Brockway '674 teaches a dissolvable cap 640 on the device to aid in introducing the device. Hence, it would have been obvious to use such a cap, to prevent injury during insertion.

Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Pohndorf et al 5353800. With respect to claim 14, Pohndorf teaches that a membrane is a known barrier to close a pressure transmitting

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carrier. Hence, it would have been obvious to modify Brockway '191 to use a membrane as the barrier, as it is merely the substitution of one known equivalent barrier for another. Claim 20 is rejected in that Pohndorf teaches that a helical catheter is a known PTC. As such, it would have been obvious to modify Brockway '191 to be a helical catheter, as it is merely the substitution of one known configuration for another.

Claims 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Itoigawa et al 5807265. Itoigawa shows an alternate PTC where the distal port is side facing. As such, it would have been obvious to modify Brockway '191 to use a side facing port, as it is merely the substitution of one known configuration for another.

Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al '191 in view of Jackson 4160448. Jackson further teaches a PTC with a fill port, to maintain a proper level of fluid in the lumen. As such, it would have been obvious to modify Brockway '191 to use such a fill port, to increase the accuracy of measurement.

Claim 6, 8, 19, and 28-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 31-34 are allowable.

Claim 6 defines over the art of record in that none of the art has a surface modification on the catheter that promotes tissue in-growth. Brockway '694 has a mesh on the housing that performs this function, but none of the art has it on the catheter.

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Claim 8 defines over the art of record in that none of the art has a surface modification on the catheter that improves the seal between the catheter and the surrounding tissue.

Claim 19 defines over the art in that none of the art has the protrusions on the catheter.

Claims 28 and 29 define over the art in that none of the art has a surface modification that performs the recited function that is ePTFE or a polyester fabric. Claim 30 define over the art in that none of the art has a surface modification that performs the recited function that is ePTFE or a polyester fabric.

Claims 31-34 define over the art of record in that none of the art has the barrier and fluid that act as a low pass filter, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
Art Unit 3735

RLN
March 28, 2007

